UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/590,542	08/25/2006	Mark G. Bock	21654P	9778	
MERCK AND	7590 04/27/200 CO., INC	9	EXAMINER		
PO BOX 2000		MCDOWELL, BRIAN E			
RAHWAY, NJ	0/065-090/		ART UNIT	PAPER NUMBER	
			1624		
			MAIL DATE	DELIVERY MODE	
			04/27/2009	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

		Applicati	on No.	Applicant(s)				
Office Action Summary			42	BOCK ET AL.				
			•	Art Unit				
		BRIAN M	CDOWELL	1624				
Period fo	The MAILING DATE of this communica or Reply	ntion appears on th	e cover sheet with the o	correspondence ad	ddress			
WHIC - Exte after - If NC - Failu Any	ORTENED STATUTORY PERIOD FOR CHEVER IS LONGER, FROM THE MAI asions of time may be available under the provisions of SIX (6) MONTHS from the mailing date of this communible period for reply is specified above, the maximum statuter to reply within the set or extended period for reply will reply received by the Office later than three months after ded patent term adjustment. See 37 CFR 1.704(b).	LING DATE OF TI 37 CFR 1.136(a). In no ex- ication. ory period will apply and w l, by statute, cause the app	HIS COMMUNICATION ent, however, may a reply be tin ill expire SIX (6) MONTHS from dication to become ABANDONE	N. nely filed the mailing date of this of (35 U.S.C. § 133).	·			
Status								
1) 又	Responsive to communication(s) filed	on 4/6/2009						
-	•	)∏ This action is r	on-final					
3)		<b>—</b>		osecution as to the	e merits is			
٥/ك	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposit	ion of Claims	, , , , , , , , , , , , , , , , , , ,	<b>,</b> , .					
· ·		ication						
· —	Claim(s) <u>1-9</u> is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.							
		withdrawn from CC	risideration.					
	Claim(s) is/are allowed.							
	Claim(s) <u>1-3,5,6,8 and 9</u> is/are rejected.							
-	Claim(s) <u>4 and 7</u> is/are objected to.							
8)[_]	Claim(s) are subject to restriction	n and/or election i	equirement.					
Applicat	ion Papers							
9)	The specification is objected to by the E	Examiner.						
10)	The drawing(s) filed on is/are: a	)∭ accepted or b	objected to by the	Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).								
	Replacement drawing sheet(s) including th	e correction is requi	ed if the drawing(s) is ob	jected to. See 37 C	FR 1.121(d).			
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.								
Priority ι	ınder 35 U.S.C. § 119							
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>								
2) Notice (3) Inform	t(s)  e of References Cited (PTO-892)  e of Draftsperson's Patent Drawing Review (PTC  mation Disclosure Statement(s) (PTO/SB/08)  r No(s)/Mail Date	)-948)	4) Interview Summary Paper No(s)/Mail D 5) Notice of Informal F 6) Other:	ate				

/BEM/

#### **DETAILED ACTION**

#### Status of Claims

Claims 1-9 are pending in the instant application.

## Status of Specification

Applicant's amendment of the abstract, see Remarks, filed 4/6/2009, with respect to the objection set forth in the Non-Final Office Action mailed 1/5/2009, has been fully considered and the objection has been overcome.

## Status of Claim Objections

#### The objection of claim 1 is still maintained.

Applicant's amendment of claim 1 see Remarks, filed 4/6/2009, with respect to the objection set forth in the Non-Final Office Action mailed 1/5/2009, has been fully considered but is not found persuasive. The examiner currently does not see any amendment to claim 1 (see page 1, line 13, next to last line on page), therefore the objection is maintained. It currently reads "and (5) heterocycle...". Instead, it should read "and (4) heterocycle...". Appropriate correction is required.

## Status of Rejections

# 35 USC § 112 (2<sup>nd</sup> Paragraph)

Applicant's amendment of claim 8 see Remarks, filed 4/6/2009, with respect to the rejection set forth in the Non-Final Office Action mailed 1/5/2009, has been fully considered and the rejection has been overcome.

## **Double Patenting**

Applicant's filing of the appropriate terminal disclaimer (in reference to the double patenting rejection of claims 1-9) see Remarks, filed 4/6/2009, with respect to the rejection set forth in the Non-Final Office Action mailed 1/5/2009, has been fully considered and the rejection has been overcome.

## 35 USC § 103

# The 103 rejection is still maintained.

Applicant's arguments of claims 1-3, 5, 6, 8, and 9 see Remarks, filed 4/6/2009, with respect to the rejection set forth in the Non-Final Office Action mailed 1/5/2009, have been fully considered but are not found persuasive.

Applicant is reminded on how to obviate this rejection:

(3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104

Therefore, the appropriate oath or declaration is needed to obviate this rejection.

Application/Control Number: 10/590,542 Page 4

Art Unit: 1624

# 35 USC § 112 (1st Paragraph)

## The 112 rejection is still maintained.

Applicant's arguments of claims 1, 2, and 9 see Remarks, filed 4/6/2009, with respect to the rejection set forth in the Non-Final Office Action mailed 1/5/2009, have been fully considered but are not found persuasive.

Again, as mentioned in the previous office action, applicant has provided sufficient support for how to make and use compounds where  $R^4$  is unsubstituted or substituted  $C_{1-6}$  alkyl, wherein the groups in which said alkyl may be substituted with include halogen, nitro, cyano, and  $SO_2R^d$ 

The specification gives some *in vitro* test results on Bradykinin inhibitory effects of a limited number of preferable compounds, however it is too homogeneous to provide a clear evaluation of which moieties attached to the alkyl group out of the many claimed might affect potency to a large or small degree. The pharmaceutical art is unpredictable and target compounds need to be individually assessed for viability. Extremely broad generalizations as found in the instant claims are in contradiction with the basis of quantitative structure-activity-relationship (QSAR).

For example, applicant says that  $C_{1-6}$  alkyl can be substituted with  $NR^bR^c$ , wherein  $R^bR^c$  may form a heterocyclic ring. The following compound may fall within the scope of claims 1, 2, and 9 then:

Application/Control Number: 10/590,542 Page 5

Art Unit: 1624

Has applicant shown one of ordinary skill in the art how to make and subsequently use this compound as a Bradykinin inhibitor? If so, applicant may be entitled to other substituents.

#### Conclusion

No claims are allowed.

Claims 4 and 7 are objected to as being dependent upon a rejected or objected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Potential Reasons for Allowance

Claims 4 and 7 embrace novel compounds wherein R<sup>4</sup> is a 6-membered heteroaryl ring or a substituted isoxazolyl group.

The limitations listed supra represent the limitations that are not taught or fairly suggested by the prior art. The closest prior art is by Kuduk *et al.* (WO 2004/019868).

Art Unit: 1624

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRIAN MCDOWELL whose telephone number is (571)270-5755. The examiner can normally be reached on Monday-Thursday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Application/Control Number: 10/590,542 Page 7

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. M./

Examiner, Art Unit 1624

/James O. Wilson/ Supervisory Patent Examiner, Art Unit 1624